LEXSEE 796 F.2D 443

BAUSCH & LOMB, INC., Appellant, v. BARNES-HIND/HYDROCURVE, INC., and BARNES-HIND INTERNATIONAL, INC., Appellees

No. 85-2578

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

796 F.2d 443*; *1986 U.S. App. LEXIS 20297*; *230 U.S.P.Q. (BNA) 416

July 14, 1986

PRIOR HISTORY: [**1] Appealed from: U.S. District Court for the Northern District of California,

Judge Aguilar.

COUNSEL: Laurence H. Pretty, Pretty, Schroeder, Brueggemann & Clark, of Los Angeles, California, argued for Appellant. With him on the brief was Craig S. Summers. Bernard D. Bogdin and Howard S. Robbins, Bausch & Lomb, Inc., of Rochester, New York, were also on the brief.

John M. Calimafde, Hopgood, Calimafde, Kalil, Blaustein & Judlowe, of New York, New York, argued for Appellees. With him on the brief were Eugene J. Kalil and Dennis J. Mondolino. Gilbert W. Rudman, Revlon Incorporated, of Tuckahoe, New York, of Counsel.

JUDGES: Markey, Chief Judge, Friedman, Circuit Judge, Nichols, Senior Circuit Judge.

OPINION BY: NICHOLS

OPINION

[*444] NICHOLS, Senior Circuit Judge.

Appellant Bausch & Lomb, Inc. filed suit in the United States District Court for the Northern District of California, alleging that appellee Barnes-Hind/Hydrocurve, Inc. and Barnes-Hind International, Inc. (hereinafter Barnes-Hind) infringed *patent No. 4,194,814 ('814 patent)* in the manufacture and sale of its laser-marked contact lens. Barnes-Hind denied infringement and counterclaimed that the *'814 patent* was invalid, [**2] void, and unenforceable. In No. C-83-20283-RPA, Judge Aquilar found the patent invalid for obviousness and not infringed. We vacate and remand.

[*445] Appellee Barnes-Hind relied to a large extent on deposition testimony which was never introduced into evidence. Because this testimony was not in evidence, it would have been improper for us to consider it and, therefore, we did not. This eliminated much of Barnes-Hind's arguments on appeal.

Background

1. *The Technology*

Vision correcting contact lenses have become familiar; hard contact lenses were introduced in the early 1950's and soft lenses in 1971. Toric contact lenses, which correct for the eye condition known as astigmatism, have a similar history of usage: hard lenses from the early 1950's and soft from the first half of the 1970's. Toric lenses differ from standard contact lenses in having a prism base, *i.e.*, one edge portion of the lens is thicker. Proper prescription and fitting of toric lenses on the cornea of the eye requires alignment of a central lens axis with this prism base. Markings on the contact lens surface greatly facilitate the fitting process.

Inks and other substances have [**3] been used since the early 1950's, however, those marking procedures suffer several disadvantages: difficulty of accurate application with possible FDA disapproval; possibility of dissolution, blurring, and allergic reactions. Mechanical marking, as with a sharp scribing tool or an abrading tool such as a dental bur, is also available, but not without its problems: inaccurate and inconsistent positioning of the mark, lens damage, inadequate visibility, and the expense and time involved.

2. *The Patent*

The *'814 patent*, entitled Transparent Opthalmic Lens having Engraved Surface Indicia, discloses an engraved contact lens and provides a method of engraving using a source of high intensity electro-magnetic energy, such as a laser. The mark, not as deep as the lens is thick, is surrounded by a smooth surface of unsublimated or unaffected polymer material with the result that edges of the markings do not inflame or irritate the eyelid of the lens wearer.

The claims in suit are 1, 2, and 7. Claim 1 provides:

> An ophthalmic lens adapted to be placed in direct contact with eye tissue formed of a transparent cross-linked polymer material, said lens being characterized by identifying [**4] indicia engraved in a surface thereof by subjecting said lens to a beam of radiation emerging from a laser having an intensity and wavelength at least sufficient to sublimate said polymer and form depressions in said lens surface to a depth less than the thickness of said lens, said lens having a smooth surface of unsublimated polymer material surrounding said depressions, and by varying in a predetermined manner the point at which said laser beam impinges upon said lens surfaces to engrave said identifying indicia in said lens surface.

Claim 2 depends from claim 1 with the limitation that the lens is formed by a cross-linked hydrophilic (water loving) polymer. Claim 7, a product claim, is similar to claim 1 but defines the depressions as relieved zones.

3. *The Dispute*

In February 1976, Mr. Donald Hager, then production manager at the Milton Roy Company, a manufacturer of soft contact lenses which was purchased by appellant Bausch & Lomb in 1979, sent to Carco, Inc., a distributor of laser equipment, six soft contact lenses for laser marking. At least two lenses were successfully marked. Around September 1976, Dr. David Fisher and Mr. James A. McCandless, also [**5] of Milton Roy Company, met with Mr. Hager to debrief him on the work. Soon thereafter, Mr. Hager resigned.

Dr. Fisher and Mr. McCandless continued to work on the lens-marking system, and in November 1977 filed an application for the patent in suit, listing themselves and Mr. Hager as inventors. Mr. Hager declined to execute the patent application, being at that time the employee of another lens manufacturing company, Sauflon [*446] International, Inc. and saying that he had not "invented anything in connection with laser marking of contact lens." He further said that he could not execute documents, under oath or otherwise, that represent the contrary. The Patent and Trademark Office (PTO) initially, and on a second occasion, rejected all the claims as obvious over two prior art U.S. patents to Brucker (No. 3,833,786) (teaching the use of a laser to fenestrate, *i.e.*, make holes, in contact lens to allow circulation of fluid through the lens) and to Caddell (No. 3,549,733) (disclosing the use of a laser to remove plastic from the surface of a printing plate to form a pattern). The PTO later issued the patent in 1980 as limited to a transparent cross-linked polymer having [**6] a smooth surface around the mark. Mr. Hager did sign as inventor in 1982. Meanwhile, Milton Roy commenced manufacture and marketing of laser-marked soft contact lenses in 1978.

Barnes-Hind's predecessor, Continuous Curve, Inc., introduced under the trademark HYDROCURVE a line of soft toric lenses around 1975-76 that were marked with an indentation by a bur. In 1981, Barnes-Hind offered a soft toric lens marked by a laser.

Bausch & Lomb filed suit, contending that certain laser-marked contact lenses manufactured and sold by Barnes-Hind infringe claims 1, 2, and 7 of the *'814 patent*. Barnes-Hind denied infringement and counterclaimed that the patent was invalid, void, and unenforceable. The parties narrowed the issue of infringement to whether the marks on the HYDROCURVE lenses are surrounded by a smooth surface of unsublimated polymer material with respect to claims 1 and 2 or a smooth and unaffected surface for claim 7.

4. *The District Court Proceedings*

The district court determined that Barnes-Hind "proved by clear and convincing evidence that the patent in suit (4,194,814) and each of its claims is invalid and therefore void." It concluded that the differences between [**7] the claims and the prior art would have been obvious, finding that "the fact that the claimed subject matter of the patent in suit was obvious to Mr. Hager is most indicative of the obviousness of the invention," and that "Dr. Brucker's experiments in laser marking contact lenses are further evidence in support of this court's finding of obviousness." The court further concluded that scanning electron microscope (SEM) photographs, showing "that the surface of these lenses surrounding the laser mark are not 'smooth and unsublimated' or 'unaffected' as those terms were defined by plaintiff [appellant] during the processing of the patent in suit," demonstrated lack of infringement in any case. Bausch & Lomb appealed.

Opinion

The judgment is premised on several legal errors: (1) disregard of the presumption of validity established by *35 U.S.C. § 282*; (2) absence of the factual findings on the four inquiries mandated by *Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. (BNA) 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)*; and (3) improper claim construction leading to the conclusion of noninfringement. We vacate the court's opinion [**8] and remand for a determination consistent with this opinion.

1. *Presumption of Validity*

A patent shall be presumed valid, and each claim shall be presumed valid independently of the validity of other claims. *35 U.S.C. § 282*. The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence. *Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 872, 228 U.S.P.Q. (BNA) 90, 97 (Fed. Cir. 1985)*; *Jones v. Hardy, 727 F.2d 1524, 220 U.S.P.Q. (BNA) 1021 (Fed. Cir. 1984)*.

The record contains no reference to this statutory presumption of validity, nor does it appear that the district court considered separately the validity of the three claims at issue. By merely holding that "defendants have proved by clear and convincing evidence that the patent in suit (4,194,814) and each of its claims is invalid [*447] and therefore void," the district court improperly denied the *'814 patent* its statutory presumption of validity as to each claim.

The district court thought the examiner had been [**9] misled. Barnes-Hind argued and argues here that Bausch & Lomb (or rather its later acquired company Milton Roy) misled the examiner during prosecution. Appellees assert that "if the examiner had been correctly and forthrightly informed of Hager's and McCandless' opinions, the chemistry of the Brucker lens, and the teaching of the Caddell patent, he would not have issued the patent." The record, however, does not support this assertion.

The examiner did know of Hager's temporary refusal to execute the application during prosecution and, as discussed more fully *infra*, a determination of nonobviousness is based, *inter alia*, on the opinion of a hypothetical person of ordinary skill in the art, not on the inventors' opinion. The weight to be attached to Hager's refusal cannot be exaggerated as the court below has done without clear error in view of Hager's self interest as an employee of a competitor and his later change of position. Instances of inventors refusing even to cooperate in obtaining issuance of a patent to be owned by an assignee are common and machinery is provided in [**10] *37 C.F.R. § 1.47* to deal with them. *Section 1.47* provides that either a joint inventor or a proper assignee may file the application without the consent or signature of the inventor, just so the oath or declaration is accompanied by a petition including proof of pertinent facts. It is clear, therefore, that the PTO does not allow the inventor to erect that type of obstacle to obtaining patent protection. Such forethought is necessary, as otherwise an inventor's changed self interest might nullify a proper assignment. The district court's heavy reliance on Mr. Hager's assertions, if persisted in, would allow a co-inventor another chance at sabotage if the first effort has failed.

Finally, the examiner, who with the deference we owe governmental officials we assume has some expertise in interpreting the references and some familiarity with the level of skill in the art, *American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359, 220 U.S.P.Q. (BNA) 763, 770* (Fed. Cir.), *cert. denied, 469 U.S. 821, 105 S. Ct. 95, 83 L. Ed. 2d 41 (1984)*, did have the Brucker and Caddell patents before him. Barnes-Hind's "misleading the examiner" contention [**11] is insufficiently supported to overcome the presumption of validity.

As a final matter, we recognize, as the district court did not, that when the prior art before the court is the same as that before the PTO, the burden on the party asserting invalidity is more difficult to meet. *American Hoist, 725 F.2d at 1359, 220 USPQ at 770*.

2. *Graham Findings*

Obviousness under *35 U.S.C. § 103* is a question of law based on the underlying factual inquiries set forth in *Graham v. John Deere Co., 383 U.S. 1, 17, 15 L. Ed. 2d 545, 86 S. Ct. 684, 148 U.S.P.Q. (BNA) 459 (1966)*: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of secondary considerations. *See, e.g., Loctite, 781 F.2d at 872, 228 USPQ at 97-98*.

The *Loctite* court further stated:

> [**12] In patent cases, the need for express *Graham* findings takes on an especially significant role because of an occasional tendency of district courts to depart from the Graham test, and from the statutory standard of obviousness that it helps determine, to the tempting but forbidden zone of hindsight. Thus we must be convinced from the opinion that the district court actually applied *Graham* and must be presented with enough express and necessarily implied findings to know the basis of the trial court's opinion.

Id., 228 U.S.P.Q. at 98.

Here, as in *Loctite* and in *Jones*, we are not convinced that the district court applied the *Graham* findings. Instead, it found Mr. Hager's opinion that the subject [*448] matter was obvious "most indicative of the obviousness of the invention." This was legal error.

Unlike the district court, we have the benefit of the very clear exposition of the law in *Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454, 227 U.S.P.Q. (BNA) 293, 297-98 (Fed. Cir. 1985)*:

> [**13] The issue of obviousness is determined entirely with reference to a *hypothetical* "person having ordinary skill in the art." It is only that hypothetical person who is presumed to be aware of all the pertinent art. The actual inventor's skill is irrelevant to this inquiry, and this is for a very important reason. The statutory emphasis is on a person of *ordinary* skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something -- call it what you will -- which sets them apart from the workers of *ordinary* skill, and one should not go about determining obviousness under *§ 103* by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelation of references. [Emphasis in original.]

In this regard then, the district court erred at least three times: it relied too heavily on the alleged opinion of one who was an inventor and patentee, and misused that opinion as a substitute for determining the level of skill of the hypothetical person of ordinary skill and what that person would have been able to do when in possession [**14] of the prior art, the scope and contents of which the court should also have determined.

The court also engaged in improper hindsight analysis to conclude the *'814 patent* would have been obvious. The court essentially adopted Barnes-Hind's argument that "the concept of forming ridgeless depressions having smooth rounded edges using a laser beam to vaporize the material is explicitly disclosed in the Caddell patent. *This is exactly the same process claimed in the patent-in-suit and practiced by the plaintiff.*"

Barnes-Hind selected a single line out of the Caddell specification to support the above assertion: "one way in which this [forming ridgeless depressions] can be achieved is to use a laser with high enough intensity to vaporize the plate material without melting it." Col. 5, lines 53-54. This statement, however, was improperly taken out of context. As the former Court of Customs and Patent Appeals held:

> It is impermissible within the framework of *section 103* to pick and choose from any one reference only so much of it as will support a given position to the exclusion [**15] of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

In re Wesslau, 53 C.C.P.A. 746, 353 F.2d 238, 241, 147 U.S.P.Q. (BNA) 391, 393 (CCPA 1965); *see also In re Mercier, 515 F.2d 1161, 1165-66, 185 U.S.P.Q. (BNA) 774, 778 (CCPA 1975).*

A full appreciation of Caddell's statement requires consideration of the immediately following sentences in the same paragraph and the paragraph after that. Viewed in that context, it is apparent that Caddell's ideal printing plate would have no ridges around the depression. The use of a high intensity laser is offered as a possible means to achieve the goal but is limited by several disadvantages. To overcome these disadvantages, Caddell suggests the use of a special class of polymer that forms ridgeless depressions. A complete reading demonstrates quite clearly that Caddell is setting up a strawman and pointing out its disadvantages to highlight the advantages of Caddell's invention, that special class of polymers. The district court improperly viewed an isolated line in Caddell in light of the teaching of the *'814 patent* to hold for obviousness. [**16] This is improper hindsight analysis.

The district court also failed to consider the Caddell reference in its entirety and thereby ignored those portions of the reference that argued against obviousness. *W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1550, 220 U.S.P.Q. (BNA) 303, 311 (Fed. Cir. 1983), cert. denied, 469 U.S. 851, 105 S. Ct. 172, 83 L. Ed. 2d 107 (1984).* [*449] Caddell compared the ridge formation of his special class of polymers against, *inter alia*, Lucite, a copolymer composed of ethyl acrylate with methylmethacrylate -- very similar to the chemical referred to in the *'814 patent* -- and found that *only* his special class formed depressions without ridges. Thus, Caddell actually taught away from laser etching of soft contact lenses.

As further evidence of obviousness, the district court relied on Dr. Brucker's experiments in laser marking contact lenses. This too was error, in this case clearly erroneous factual error. The record does not support, indeed it contradicts, the supposition that Dr. Brucker had engaged in laser marking of soft contact lenses at the time of the present invention. On page [**17] 385 of the Appendix, in reply to Mr. Calimafde's question "when did Continuous Curve begin to experiment with laser marking of soft contact lenses?", Dr. Brucker replied "I believe it was in '79 -- '79, '80, somewhere in that area." The filing date of the *'814 patent* was November 10, 1977. Brucker's 3,833,786 patent for a method of fenestrating (putting windows in) contact lenses applies according to its claims to such lenses, both soft and hard. However, the record reflects that the need for such fenestration was as a mode of escape for fluid accumulating between the lens and the eye. Such a need does not exist respecting the soft lenses, the principal subject of the claims in suit, of which claim 2 is expressly limited to soft lenses. They, being hydrophilic, absorb the fluid.

In sum, the district court improperly determined the *'814 patent* was obvious: it failed to make the *Graham* inquiries, it improperly focused on what was obvious to the inventor, it engaged in hindsight analysis, and it considered evidence that was not prior art. This court, as an appellate court, may not make the required *Graham* factual findings, and must therefore remand that determination to [**18] the district court. The district court should not ignore the four-part analysis the authorities require.

a. *The scope and content of prior art*

To determine whether a reference is within the scope and content of the prior art, first determine if the reference is within the field of the inventor's endeavor. If it is not, then next consider whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Richard M. Deminski, 796 F.2d 436*, slip op. at 9 (Fed. Cir. 1986); *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 U.S.P.Q. (BNA) 871, 876 (Fed. Cir. 1983). Orthopedic Equipment Co., Inc. v. United States, 702 F.2d 1005, 1008-11, 217 U.S.P.Q. (BNA) 193, 196-97 (Fed. Cir. 1983)* focused on the claims in suit, the art the PTO applied to the claims, and the nature of the problem confronting the inventor. Further, the art must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved.

b. *The differences* [**19] *between the claimed invention and the prior art*

The court must view the claimed invention *as a whole. See, e.g., Jones, 727 F.2d at 1527-28, 220 USPQ at 1024*. We add, as a cautionary note, that the district court appeared to distill the invention down to a "gist" or "core," a superficial mode of analysis that disregards elements of the whole. It disregarded express claim limitations that the product be an ophthalmic lens formed of a transparent, cross-linked polymer and that the laser marks be surrounded by a smooth surface of unsublimated polymer. *See also, ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 221 U.S.P.Q. (BNA) 929 (Fed. Cir. 1984).*

c. *Level of ordinary skill in the art*

In *Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 697, 218 U.S.P.Q. (BNA) 865, 868-69 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043, 79 L. Ed. 2d 173, 104 S. Ct. 709, 224 U.S.P.Q. (BNA) 520 (1984)*, the court listed [**20] six factors relevant to a determination of the level of ordinary skill: educational level of the inventor, type of problems encountered in the art, prior art solutions, rapidity of innovation, sophistication [*450] of technology, and educational level of active workers in the field. As to educational level of the inventor, *see Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 227 U.S.P.Q. (BNA) 293 (Fed. Cir. 1985); Orthopedic Equipment Co. v. All Orthopedic Appliances, 707 F.2d 1376, 1382, 217 U.S.P.Q. (BNA) 1281, 1285 (Fed. Cir. 1983)* ("Although the educational level of the inventor may be a factor in determining the level of ordinary skill in the art, it is by no means conclusive.")

d. *Objective indicia of obviousness*

Such "secondary considerations," when present, must always be considered. *Stratoflex, 713 F.2d at 1538. See also Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1026-28, 226 U.S.P.Q. (BNA) 881, 887-88 (Fed. Cir. 1985).* Such evidence includes commercial success, long [**21] felt but unresolved needs, and failed attempts. *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 895-96, 221 U.S.P.Q. (BNA) 669, 675* (Fed. Cir.), *cert. denied , 469 U.S. 857, 83 L. Ed. 2d 120, 105 S. Ct. 187 (1984).*

We shall vacate the trial court's opinion and remand for an obviousness determination consistent with this opinion.

3. *Infringement*

The parties narrowed the infringement issue for trial to the question whether the surface of Barnes-Hind lenses surrounding the laser mark is "smooth and unsublimated" or "unaffected." The district court concluded that "the laser-engraved depressions in the surface of the HYDROCURVE II lenses have been examined by scanning electron microscope. These photographs show that the surface of these lenses surrounding the laser mark are not 'smooth and unsublimated' or 'unaffected' as those terms were defined by plaintiff during the prosecution of

the patent in suit." Appellant Bausch & Lomb argues on appeal that the trial court's approach of assessing smoothness at the very high levels of magnification obtainable by a SEM exceeds the level of smoothness required in the claims. We agree.

[**22] Because the first step in determining infringement is claim construction, improper claim construction can distort the entire infringement analysis. *Moeller v. Ionetics, Inc., 794 F.2d 653*, slip op. at 7 (Fed. Cir. 1986). Such a distortion occurred below.

Disputed issues such as the meaning of the term "smooth," should be construed by resort to extrinsic evidence such as the specification, other claims, and the prosecution history. Here, resort to the specification clearly demonstrates that "smooth" meant that "the edges of the craters neither inflame nor irritate the eyelid of the lens wearer * * *. The markings provided on the lens surface in accordance with this invention * * * are not perceived by the lens wearer * * *." The prosecution history supports this construction. A reading of the amendment and its accompanying remarks demonstrates that smooth means the absence of a ridge that "would scratch either the eye or eyelid and would lead to infection." There is no indication that smooth means absolutely ridge-free. (This review of the prosecution history also [**23] leads us to disagree with Barnes-Hind's final argument that the prosecution history estops Bausch & Lomb from asserting infringement against the allegedly ridged HYDROCURVE lens.) Testimony from Dr. Mandell, Bausch & Lomb's expert in the field of contact lenses, indicates that to a person of ordinary skill in the art, smooth would mean an absence of "roughness or significant elevation" so that a wearer "would not feel it with the [eye]lid." Further, there is testimony that a person of ordinary skill in the art would use an optical microscope, not an SEM, to gauge the relative smoothness of an etched contact lens.

We hold that smooth means smooth enough to serve the inventor's purposes, *i.e.*, not to inflame or irritate the eyelid of the wearer or be perceived by him at all when in place. Accordingly, we vacate the district court's conclusion that the surface of the HYDROCURVE lenses are not smooth or unaffected, and remand for a determination of infringement based on the proper construction of and proper test for smooth.

[*451] *Conclusion*

We vacate the district court's determination that the *'814 patent* is invalid and remand for a reconsideration of validity in [**24] light of the presumption of validity and the *Graham* findings on obviousness. We further vacate the decision of noninfringement and remand for proper claim construction and infringement analysis.

VACATED AND REMANDED.